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IN THE

Supreme Court of the United States

EBAY, INC. and HALF.COM, INC.,

Petitioners,

—v.—

MERCEXCHANGE, L.L.C.,

Respondent.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

AMICUS CURIAE BRIEF OF TEVA PHARMACEUTICALS USA, INC. IN SUPPORT OF NEITHER PARTY

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INTEREST OF THE *AMICUS CURIAE*

Amicus curiae Teva Pharmaceuticals USA, Inc. ("Teva") is a recognized leader in the research, development, manufacture and distribution of low-cost generic pharmaceuticals.[1] Teva's generic drug products are used by consumers throughout the United States, and are available through drugstores, hospitals, managed care entities, and government agencies. As a result of their research and development activities, Teva and its affiliates have been awarded more than 150 U.S. patents, and currently have hundreds of patent applications pending before the United States Patent and Trademark Office.

Teva has no interest in any party to this litigation or any stake in the outcome of this case. Nor does Teva have a position as to which party should ultimately prevail. The questions to be decided in this case, however, are important to Teva as both a holder of valuable patents and as a party that is frequently the subject of patent infringement suits intended to keep its generic drugs off the market.

It is important to Teva as a patent holder that injunctions remain in the arsenal of remedies that district courts may employ in patent infringement

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[1] The parties have consented to the filing of this brief, and letters of consent have been filed in accordance with Supreme Court Rule 37.3. In accordance with Supreme Court Rule 37.6, *amicus curiae* states that this brief was not authored, in whole or in part, by counsel to any party, and no monetary contribution to its preparation or submission was made by any person or entity other than the *amicus curiae*.

actions. At the same time, Teva believes that a blanket rule requiring the grant of an injunction in every case in which infringement is found, subject only to a narrow exception for "exceptional cases" implicating public health, will lead to inequitable results, and is contrary to the letter and spirit of 35 U.S.C. § 283. Teva submits this *amicus curiae* brief because it believes that, as a pharmaceutical company, it can offer the Court a different perspective from that of the parties to this case concerning the significant inequities that would result from an automatic injunction rule.

SUMMARY OF THE ARGUMENT

One of the questions before the Court is "[w]hether the Federal Circuit erred in setting forth a general rule in patent cases that a district court must, absent exceptional circumstances, issue a permanent injunction after a finding of infringement." A rigid rule requiring automatic injunctions in all patent cases absent "exceptional circumstances" is contrary to the explicit language of 35 U.S.C. § 283 as well as this Court's precedents. Such a rule would require district courts to grant injunctions in situations in which equity dictates that they should not.

In particular, a basic principle of equity is that an injunction should not issue if the conduct to be restrained is merely "trifling" and causes no injury to the plaintiff. It has become commonplace in the pharmaceutical industry, however, for a charge of patent infringement to be based on the presence of a *de minimis* or "trifling" amount of a patented substance in a drug product that is otherwise not patented. One district court has already recognized that granting an injunction against the sale of a drug product that

infringes a patent solely because the product contains a minute quantity of the patented material would amount to "a travesty of equity." *SmithKline Beecham Corp. v. Apotex Corp.*, 247 F. Supp.2d 1011, 1045-46 (N.D. Ill. 2003), *aff'd on other grounds*, 365 F.3d 1306 (Fed. Cir. 2004). A rigid rule that compels the grant of an injunction except in "exceptional circumstances" would cast in concrete the "travesty" that the district court recognized.

Such a draconian application of the injunctive remedy is not required by statute or by precedent. Indeed, this Court has made clear that district courts have broad discretion to grant or deny injunctive relief. *See, e.g., Weinberger v. Romero-Barcelo*, 456 U.S. 305, 311-13 (1982). The traditional equitable discretion afforded to district courts may not be limited absent "a clear and valid legislative command." *Id.* at 313 (quoting *Porter v. Warner Holding Co.*, 328 U.S. 395, 398 (1946)). With respect to patent cases, Congress has issued no such directive limiting the discretion of district courts to award or deny injunctions. On the contrary, 35 U.S.C. § 283 expressly preserves the district courts' traditional equitable discretion by providing that injunctions in patent cases "may" be granted "in accordance with principles of equity."

A ruling confirming that, pursuant to section 283, injunctions in patent infringement actions are available, but not mandatory, will ensure that the decision whether to grant an injunction in a patent infringement action, as in any other action, will be left to the discretion of the district courts to be exercised in accordance with traditional equitable principles.

ARGUMENT

I. CONGRESS DETERMINED THAT DISTRICT COURTS SHOULD EXERCISE DISCRETION IN GRANTING OR DENYING INJUNCTIONS IN PATENT CASES

As this Court made clear long ago, and has confirmed on several occasions since, an injunction "'is not a remedy which issues as of course.'" *Weinberger*, 456 U.S. at 311 (quoting *Harrisonville v. W. S. Dickey Clay Mfg. Co.*, 289 U.S. 334, 337-38 (1933)). Accordingly, when Congress authorizes district courts to issue injunctions for violations of a statute, as it did in 35 U.S.C. § 283, it "hardly suggests an absolute duty to do so under any and all circumstances." *Weinberger*, 456 U.S. at 313. On the contrary, "[u]nless a statute in so many words, or by a necessary and inescapable inference, restricts the court's jurisdiction in equity, the full scope of that jurisdiction is to be recognized and applied." *Id.*

35 U.S.C. § 283 does not, either explicitly or by inference, restrict the scope of a district court's traditional equitable jurisdiction when it is fashioning relief in a patent infringement action. On the contrary, section 283 confirms that courts in patent infringement actions should consider the same equitable factors in deciding whether to issue injunctions as they would in any other case:

> The several courts having jurisdiction of cases under this title *may* grant injunctions *in accordance with the principles of equity* to prevent the violation of any right secured by patent, *on such terms as the court deems reasonable*.

(Emphasis added.)

This Court has confirmed that courts "'must presume that [the] legislature says in a statute what it means and means in a statute what it says there.'" *Dodd v. United States*, 125 S. Ct. 2478, 2482 (2005) (quoting *Conn. Nat'l Bank v. Germain*, 503 U.S. 249, 253-54 (1992)). In section 283, Congress deliberately used the phrase "may grant injunctions," rather than "must grant injunctions." This Court has construed the term "may" in similar circumstances as "either conferring or confirming a degree of equitable discretion." *United States v. Rodgers*, 461 U.S. 677, 708 (1983) (Section 7403 of the Internal Revenue Code construed to provide courts with equitable discretion to order sales of family homes). This "common-sense" construction "conforms to the even more important principle of statutory construction that Congress should not lightly be assumed to have enacted a statutory scheme foreclosing a court of equity from the exercise of its traditional discretion." *Id.* Indeed, even when a statute includes more mandatory language, it will not be construed to require the court to grant injunctive relief under all circumstances. *See Hecht Co. v. Bowles*, 321 U.S. 321, 329-30 (1944) (statutory provision that injunctions "shall" issue for violations of the Emergency Price Control Act construed not to require issuance of an injunction in every case in which a violation is found because neither the history nor the language of the statute compelled the conclusion that "Congress had intended to make such a drastic departure from the traditions of equity practice").

The Federal Circuit has no authority to rewrite section 283 to make injunctions mandatory in patent cases. As this Court recently reiterated, courts are "not free to rewrite [a] statute that Congress has enacted.

"When the statute's language is plain, the sole function of the courts – at least where the disposition required by the text is not absurd – is to enforce it according to its terms.'" *Dodd*, 125 S. Ct. at 2483 (2005) (quoting *Hartford Underwriters Ins. Co. v. Union Planters Bank, N.A.*, 530 U.S. 1, 6 (2000)). *See also Tyler v. Cain*, 533 U.S. 656, 663 n.5 (2001) ("Even if we disagreed with the legislative decision . . . we do not have license to question the decision on policy grounds.").

Indeed, earlier Federal Circuit decisions recognized that section 283 made injunctions in patent cases discretionary, not automatic. For example, in *Joy Techs., Inc. v. Flakt, Inc.*, 6 F.3d 770, 772 (Fed. Cir. 1993), the Federal Circuit acknowledged that district courts are "given broad discretion under 35 U.S.C. § 283 (1988) to determine whether the facts of a case warrant the grant of an injunction and to determine the scope of the injunction." Similarly, in *Roche Prods., Inc. v. Bolar Pharms. Co.*, 733 F.2d 858, 865 (Fed. Cir. 1984), the Federal Circuit stated that "[s]ection 283, by its terms, clearly makes the issuance of an injunction discretionary." The *Roche* emphasized that "[i]f Congress wants the federal courts to issue injunctions without regard to historic equity principles, it is going to have to say so in explicit and even shameless language." *Id.* at 867.

Before the creation of the Federal Circuit and its nationwide jurisdiction over appeals in patent cases, other circuit courts likewise acknowledged that section 283 gave district courts discretion to grant or deny injunctions based on traditional equitable principles. For example, in *Foster v. Am. Mach. & Foundry Co.*, 492 F.2d 1317, 1324 (2d Cir. 1974), the court stated:

> An injunction to protect a patent against infringement, like any other injunction, is an equitable remedy to be determined by the circumstances. 35 U.S.C. § 283. It is not intended as a club to be wielded by a patentee to enhance his negotiating stance.

To the extent the decision below requires that, absent an imminent public health risk, an injunction must be granted in every case in which patent infringement is found, it improperly circumscribes a district court's equitable discretion, which Congress expressly preserved in 35 U.S.C. § 283. Teva urges this Court to confirm that district courts have discretion to grant – or deny – injunctive relief on a case by case basis in accordance with equitable principles.

II. AN INFLEXIBLE NEAR-AUTOMATIC INJUNCTION RULE WOULD RESULT IN INJUNCTIONS THAT ARE INEQUITABLE AND CONTRARY TO THE PUBLIC INTEREST

The difference between a *per se* rule requiring a district court to grant an injunction in virtually every action in which it finds infringement and a rule that permits the exercise of judicial discretion has very real consequences to the generic drug industry and to the public, which benefits from the availability of low cost drug products.[2] One recurring situation in which equity counsels against the grant of an injunction arises when the conduct to be enjoined causes no harm to the

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[2] *See, e.g.*, Fed. Trade Comm'n, *Generic Drug Entry Prior to Patent Expiration* (2002), *available at* http://www.ftc.gov/gs/2002/07/genericdrugstudy.pdf.

plaintiff. Specifically, an automatic injunction rule could force district courts to enjoin the sale (and, accordingly, the use by consumers) of generic drug products that are found to contain *de minimis* amounts of a patented substance, even though the presence of such substances creates no benefit for the manufacturer and causes no economic harm to the patent owner. In a time when the rise in medical costs substantially outpaces the rate of inflation, it is especially important that the Court not announce a rule that would unjustifiably prohibit the marketing of such products.

As background, drug products typically contain one or more "active ingredients" – chemical compounds that are effective in treating the condition for which the drug product is indicated. Only a small fraction of the pharmaceutical patents, however, claim new pharmaceutically active ingredients. *See* Correa, *Patent Laws, TRIPS, and R&D Incentives: A Southern Perspective* 9-15 (Comm'n on Macroecon. and Health, CMH Working Paper Series No. WG2:12, 2001), *available at* http://www.cmhealth.org/docs/wg2_paper12.pdf. Most pharmaceutical patents are second or third generation patents that claim, for example, processes for manufacturing previously patented compounds, particular formulations that contain previously patented compounds, or particular crystalline forms of previously patented compounds.[3] It has even become common to patent

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[3] Many pharmaceutical compounds are solids in which the molecules of the compound are arranged in three-dimensional space in a repeating pattern, referred to as a crystalline form. Some solid-state compounds can exist in more than one crystalline form. For a

the barely detectable impurities in a bulk active ingredient that are created as unwanted by-products of the manufacturing process.

After the basic compound patent on an active ingredient expires, these second and third generation patents are often asserted against potential competitors in an effort to extend the time during which the drug can be marketed free from competition. In certain of these cases, the charge of infringement is based solely on the alleged presence of a *de minimis* amount of a patented substance in a drug that is otherwise in the public domain. These minute quantities of patented materials have no, or at least no significant, therapeutic or commercial value. In fact, drug makers would prefer not to market products containing such materials, but cannot practicably remove them. Although the presence of those undesired patented materials is not commercially significant, the Federal Circuit has indicated that the sale of the bulk product containing such a material is an infringement of any patent that might cover it. *SmithKline Beecham*, 365 F.3d at 1315. The question the Federal Circuit has not decided explicitly is whether a request for injunctive relief to prevent such infringement must be granted.

Although the Federal Circuit has not addressed this issue, at least one district court has carefully considered it and has denied a request for injunction in two separate cases. In *SmithKline Beecham, supra*, Judge Posner, sitting by designation, explained in detail why granting an injunction in such circumstances would be a "travesty of equity." In that case, the drug at issue was

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general discussion see *SmithKline Beecham*, 247 F. Supp.2d at 1016-17.

the antidepressant paroxetine, which Smithkline marketed as Paxil. The basic patent on paroxetine had expired before the suit was brought, and the patent in suit was a second generation patent claiming a particular crystalline form of paroxetine, known as the "hemihydrate" form. Apotex sought FDA approval to market a generic equivalent of Paxil containing a different crystalline form of paroxetine, known as the "anhydrous" form, which was in the public domain. SmithKline nevertheless brought suit against Apotex seeking an injunction to prevent Apotex from marketing its generic Paxil product. SmithKline's claim was that although the vast bulk of Apotex's product consisted of the unpatented form, it also included a small amount of the patented hemihydrate. 247 F. Supp.2d at 1045-46.

The district court found that SmithKline would not be entitled to an injunction even if it could prove that Apotex's tablets contained the patented form, and therefore infringed its patent. The court pointed out that:

> An injunction is a substitute for an award of damages in situations in which damages are difficult to calculate or are otherwise inadequate as a remedy for the wrong done by the defendant to the plaintiff . . . . It is not to provide relief when the damages are known to be zero. . . .

Id. at 1045. The court reasoned that the presence of an inconsequential amount of the patented hemihydrate in Apotex's product would not provide "a competitive advantage that could inflict a loss on SmithKline," since Apotex's sales of the patented form would be essentially zero. *Id.* at 1046. Any economic harm that SmithKline would suffer would be due to legitimate competition from Apotex's public domain substitute:

> [A]ny injury that SmithKline sustains from the fact that minute amounts of its product creep into Apotex's generic product will be due not to the invasion of any interest that patent law protects, but merely to the fact that the existence of a public-domain substitute for a patented product injures the patentee by providing competition.

Id. at 1048. The court concluded by holding that: "To provide relief in such a case would be to invite a form of extortion." *Id.* at 1045. On appeal, the Federal Circuit affirmed the judgment, but on alternative grounds.

Similarly, in *Abbott Labs. v. Andrx Pharms., Inc.*, No. 05 C 1490, 2005 U.S. Dist. LEXIS 10846, at *9 (N.D. Ill. June 3, 2005), one of the patents in suit claimed a compound that was alleged to form as an impurity during production of the antibiotic drug clarithromycin, which Abbott marketed as Biaxin. Abbott sought a preliminary injunction barring sales of the defendants' generic Biaxin products based on the presence in those products of "trace amounts" – about one part per million – of the patented impurity. The court refused to grant a preliminary injunction based on alleged infringement of this patent because Abbott "suffers no competitive disadvantage" from the presence of a minuscule amount of the patented impurity in the defendants' products. *Id.* at *45. Accordingly, "Abbott has not suffered and could not prove monetary damages even if [the patent] had been infringed." *Id.* at *44.

Over the years, several similar patent infringement actions have been brought seeking to enjoin the marketing of generic equivalents of unpatented drugs based on the presence of minute quantities of patented

impurities. *See, e.g., Glaxo Group Ltd. v. Torpharm, Inc.*, 153 F.3d 1366, 1373-74 (Fed. Cir. 1998) (Patentee sought to bar sale of a generic equivalent to Zantac based on the alleged presence of 0.5 percent of a patented crystalline form in the accused product.). Some of these actions are currently pending. A mandatory injunction rule would not only unfairly restrain manufacturers from putting their products on the market, it would also have a deleterious impact on the public. The availability of low-cost generic pharmaceuticals results in significant savings for consumers. A broad, automatic injunction rule could force district courts to enjoin the marketing of such drugs in situations in which equity would be disserved by doing so.

The district court's approach in *SmithKline Beecham* and *Abbott* – rejecting a *per se* rule – is consistent with this Court's precedents and with older precedents from patent cases. In *Consolidated Canal Co. v. Mesa Canal Co.*, 177 U.S. 296, 302 (1900), this Court held that "it is familiar law that an injunction will not issue . . . to restrain an act the injurious consequences of which are merely trifling." This general rule that a court will not grant an injunction to prevent a "trifling" injury has been applied on several occasions by courts in patent infringement actions. For example, in *Condenser Corp. v. Micamold Radio Corp.*, 145 F.2d 878, 880 (2d Cir. 1944), the accused product was found to infringe the patent in suit, but "only lamely and spasmodically." Judge Learned Hand refused to grant an injunction, finding that:

> [I]n the case of patents as elsewhere there comes a point where what may be literally a wrong, is of too trifling importance to justify the intervention of a court. This is such a case; we will not enjoin the

> defendant's machine for a detail, obviously so useless in function. Moreover, it would be equally unwarranted to give judgment for damages or profits; for it is inconceivable that the infringement, if there is any at all . . . could add a cent to the defendant's profits, or could interfere in the slightest degree with the plaintiff's sales.

Id. (citation omitted). Similarly, in *Pratt v. United States*, 43 F. Supp. 461 (Ct. Cl. 1942), the patentee acknowledged that the accused product infringed its patent only occasionally. It argued, however, that "even if the defendant . . . did not use its [invention in an infringing manner] except by inadvertence or unskillfulness, yet the mechanism was an infringement because it was capable of so operating, and did, on occasion, so operate." *Id.* at 475. The court denied injunctive relief, finding that:

> We do not think that the monopoly of a patent covers another device, constructed in good faith to operate upon a principle different from that involved in and intended by the patent, merely because it is impossible or impracticable to construct the other device so that it can be operated without inadvertently or unskillfully, upon occasion, infringing upon the outside boundaries of what might seem literally to be within the patent.

Id. at 475-76.

The foregoing description illustrates a specific, but nevertheless highly consequential, situation in which an inflexible rule requiring the imposition of injunctive relief for patent infringement is both inequitable and contrary to the public interest. This Court should confirm that the imposition of an injunction in a patent case should be in accordance with traditional equitable principles.

CONCLUSION

For the foregoing reasons, Teva respectfully urges the Court to confirm that 35 U.S.C. § 283 "means what it says," and that district courts have discretion to grant or deny injunctions in patent cases in accordance with equitable principles. This flexible approach will prevent the issuance of injunctions that are grossly inequitable to both manufacturers and consumers.

January 26, 2006 Respectfully submitted,

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